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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,332	12/18/2000	Lawrence Blatt	MBHB00,801-F 400.003	4581
20306	7590	10/23/2003	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF			SCHULTZ, JAMES	
300 SOUTH WACKER DRIVE			ART UNIT	
SUITE 3200			PAPER NUMBER	
CHICAGO, IL 60606			1635	

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/740,332	Applicant(s) BLATT ET AL.	
	Examiner J. Douglas Schultz	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 39-55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority /Objections

This application claims priority to U.S. Patent Application number 09/504,321. The title of this application is "PREASSEMBLED HEAT EXCHANGE UNIT AND VEHICLE INCLUDING SUCH UNIT", and a review of this application indicates that the subject matter therein is not consistent with the instant subject matter; priority claims to this document are thus rejected. However, U.S. Patent Application number 09/504,231, entitled "ENZYMATIC NUCLEIC ACID TREATMENT OF DISEASES OR CONDITIONS RELATED TO HEPATITIS C VIRUS INFECTION" by the same inventors does appear to be related. If U.S. Patent Application number 09/504,231 is the proper priority document, correction is required.

Regarding priority dates of the claimed invention identified in claims 39-49, drawn to DNazymes targeted to the hepatitis C virus and modifications thereof, the earliest enabling disclosure is considered to have been set forth in the earliest claimed priority document, that of provisional application 60/083,217, filed April 27, 1998. However, the invention identified in claims 50-55, drawn to a DNzyme comprising SEQ ID NO: 9700 and modifications thereof, is first considered to be adequately supported in the disclosure of U.S. Application Number 09/817,879, filed July 7, 2000, because said application appears to set forth the first description of any sequence relating to that of SEQ ID NO: 9700, absent evidence to the contrary. Accordingly, claims 39 to 49 are granted the priority date of April 27, 1998, while claims 50-55 are granted the priority date of July 7, 2000. Should applicants disagree, applicants are invited to point out with particularity where, in any of the claimed priority documents, and by page and line number, such support exists.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-45 and 47-50 recite the limitation "the enzymatic nucleic acid molecule of claim 1", while claim 46 recites "the mammalian cell of claim 6". There is insufficient antecedent basis in the above claims for claims 1 and 6, because claims 1 and 6 have been canceled at applicants' direction in a previous amendment.

For the purposes of prosecution, claims 40-45 and 47-50 are considered to depend from claim 39, because claim 39 is the sole remaining independent claim. Claim 46 is considered to depend from claim 45, because claim 45 is the only claim preceding claim 46 that recites a mammalian cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-46, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Barber et al (U.S. Patent Number 6,043,077).

The invention of the above claims is drawn to an enzymatic nucleic acid molecule that targets hepatitis C virus (HCV), wherein said ribozyme does not require a 2'-OH group, wherein said molecule is directed to either the plus or minus strand of HCV, or wherein said molecule is between 12 and 100, or 14 and 24 nucleobases long, or is in a pharmaceutically acceptable solution, and to cells containing said molecule, wherein said molecule is human, wherein said molecule comprises a phosphorothioate modification.

Barber teaches an enzymatic nucleic acid molecule that targets hepatitis C virus (HCV) and may be made of DNA (which doesn't contain a 2'-OH, column 4, lines 24-26), wherein said molecule is directed to either the plus or minus strand of HCV, or wherein said molecule is between 12 and 100, or 14 and 24 nucleobases long, or is in a pharmaceutically acceptable solution, and to cells containing said molecule, wherein said cell is a human cell, wherein said molecule comprises a phosphorothioate modification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47, 48 and 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber et al. in view of Joyce et al. (U.S. Patent Number 5,807,718).

The invention of claims 47 and 48 is as that rejected by Barber above, wherein the molecule comprises at least one 2' sugar modification, and one nucleic acid base modification.

Barber et al. teaches DNAzymes as described above. Barber does not teach DNAzymes comprising 2' sugar or nucleic acid base modifications.

Joyce et al. teaches DNAzymes comprising 2' sugar and nucleic acid base modifications, as in table 1.

It would have been obvious to one of ordinary skill in the art to make the DNAzymes of Barber et al. with the 2' sugar and nucleobase modifications as taught by Joyce et al. One of ordinary skill in the art would have been motivated to do so, because Joyce et al. teach that such modifications can be used to enhance the bioactive half-life of such molecules, or alternatively, enhance cleavage rates. One of ordinary skill would have had a reasonable expectation of making and using such molecules, because the steps involved in making such modified oligos are taught or referenced by Joyce, and because such steps are routine to one of ordinary skill. Thus, in the absence of evidence to the contrary, the invention would have been prima facie obvious to one of ordinary skill at the time the invention was made.

Claims 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nowakowski et al. (Nat. Struct. Biol. 6 (2), 151-156 (1999)), in view of Barber et al. and Joyce et al.

The invention of the above claims is drawn to a DNAzyme targeting HCV having the sequence set forth at SEQ ID NO: 9700, wherein said DNAzyme is comprises at least one 2'-sugar modification which may be 2'-O-methyl modification, one nucleic acid base modification, or one phosphate modification which may be a phosphorothioate modification.

Nowakowski et al. teaches a DNAzyme comprising SEQ ID NO: 9700. Nowakowski et al. does not teach said DNAzyme engineered to cleave HCV, or said DNAzymes comprising at least one 2'-sugar modification which may be 2'-O-methyl modification, one nucleic acid base modification, or one phosphate modification which may be a phosphorothioate modification.

Barber teaches enzymatic nucleic acid molecules made of DNA that cleave HCV, and teaches phosphate modifications which may be a phosphorothioate modification.

Joyce et al. teaches DNAzymes comprising 2' sugar and nucleic acid base modifications, as in table 1.

It would have been obvious to one of ordinary skill in the art to make the DNAzyme of SEQ ID NO: 9700 of Nowakowski et al. and target it to the HCV target as taught by Barber, and further, to incorporate nucleobase, 2'-sugar and phosphate modifications into such a DNAzyme as taught by both Barber and Joyce et al. One of ordinary skill in the art would have been motivated to make a DNAzyme of SEQ ID NO: 9700 targeted to HCV, because Barber teaches that enzymatic nucleic acids made of DNA can be used to target HCV to inhibit viral replication, and because Nowakowski et al. teach that their DNAzyme can be engineered to target virtually any target and that such ribozymes enjoy enhanced resistance to degradation. Furthermore, one would have been motivated to modify such DNAzymes in the manner of Joyce et al. and Barber et al. because both teach that 2'-sugar modifications including 2'-O-methyl modifications, or

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nucleic acid base modifications, or phosphorothioate modifications can be used to enhance the bioactive half-life of such molecules, or alternatively, enhance cleavage rates. One of ordinary skill would have had a reasonable expectation of making and using such molecules, because the steps involved in making such modified oligos are taught or referenced by both Joyce and Barber, and because such steps are routine to one of ordinary skill. Thus, in the absence of evidence to the contrary, the invention would have been prima facie obvious to one of ordinary skill at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 39 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,482,923 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to enzymatic nucleic acids that do not require a 2'-OH moiety and which target the

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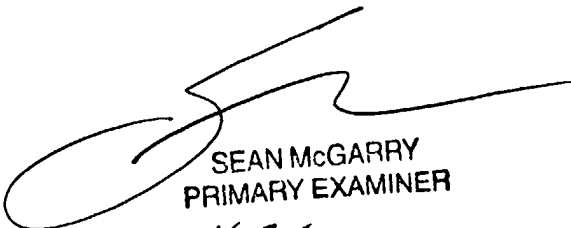
hepatitis C virus. Thus, the claim of U.S. Patent No. 6,482,923 B1 embraces claim 39 of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD



SEAN MCGARRY
PRIMARY EXAMINER
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